

Agenda item:	8
Report title:	Enhanced Triage Guidance – Single Clinical Incidents
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Action:	To consider

Executive summary

Work began in 2014 to make better use of Rule 4(4) to identify complaints and referrals that require investigation. The new Provisional Enquiries process has been rolled out and we are now beginning the next phase of the Rule 4(4) project. This project will pilot a change to the way we approach single clinical concerns.

The initial phase will focus on 'single clinical incidents', (i.e. incidents consisting of only a single point of contact between a doctor and patient) and the subsequent phase will include 'single clinical concerns' (i.e. concerns relating to more than one point of contact but only a single issue or course of treatment).

The guidance at Annexes A and B is designed for Assistant Registrars in triage to assist in identifying and processing appropriate cases but will also support the Employer Liaison Advisers in advising Responsible Officers. The guidance includes:

- a** The definition of a 'single clinical incident' and 'single clinical concern'.
- b** Criteria for when it is necessary to refer a case for investigation.

Recommendations

The Strategy and Policy Board is asked to:

- a** Agree the approach to the piloting of greater use of provisional enquiries for single clinical incidents and concerns.
- b** Approve the guidance *Single Clinical Incidents and concerns – thresholds guidance* at Annex A; and *Provisional Enquiries (Rule 4(4))* at Annex B.
- c** Note the next steps of the project.

Background

- 1 The Provisional Enquiry (PE) process was piloted from November 2014 to September 2015. In that time, 252 PEs were opened. Of these 76% (136) were closed after the PE, and 24% (44) were referred for a Stream 1 investigation. The median time to close a case in provisional enquiry is 63 days, as opposed to 245 days in stream 1. Following the success of the pilot, in July 2015, the Board agreed that it should be rolled out.
- 2 The Board also approved a second phase of the Rule 4(4) pilot to scope and plan how we streamline the way we investigate single clinical concerns.
- 3 Our data does not allow us to report reliably on the number of single clinical concerns we investigate but from previous sampling undertaken we believe it is between 15-20% of Stream 1 (400-550 cases a year)*. These cases can typically take around 183 to 234 days to complete with over 90% of these concluding with no further action being taken against the doctor. As such they indicate that better information at the triage stage could introduce a more proportionate and timely response.
- 4 We propose to take a phased approach to the use of Rule 4(4) for obtaining more information about and investigating single clinical concerns.
- 5 The first phase will pilot a new approach to dealing with single clinical incidents (incidents consisting of only a single point of contact between a doctor and patient) and 'single clinical concerns' (concerns relating to more than one point of contact but only a single issue or course of treatment) will be considered as a second phase.
- 6 Based on sampling completed so far, we have received only eight cases eligible for the pilot in four weeks using the current definition of single clinical incidents. In light of this, we suggest running a short eight week pilot based on this definition, before widening the scope to include single clinical concerns.

Single clinical concerns

- 7 In order to improve the way we handle single clinical concerns, we are developing two changes to our current process:
 - a Piloting enhanced triage guidance - Guidance including a definition of single clinical incidents and single clinical concerns and matters to consider will support triage decision makers in deciding if an investigation is necessary. The guidance sets out the factors that reduce or aggravate risk and will also be useful for

* Based on figures for 2014 ([State of medical education and practice in the UK report: 2015](#))

Employer Liaison Advisers (ELAs) when advising Responsible Officers (ROs) about whether to refer a single clinical incident or concern to the GMC.

- b** Piloting enhanced provisional enquiries process and guidance update - Where a single clinical incident or concern has not previously been raised by the doctor's RO, the provisional enquiries process will be used to seek information from the RO to help us make a more informed triage decision.
- 8** The project will reduce the impact on doctors of unnecessary investigations, speed up the handling of single clinical incidents and concerns that will enable us to respond to complaints more effectively and reduce the number of cases closed following an investigation with no action being taken against the doctor. An overview of the process is at Annex C.

Guidance

- 9** Draft guidance for decision makers is at Annex A. The guidance includes:
- a** A definition of single clinical incidents and concerns.
 - b** The factors that aggravate or mitigate a concern in order to support ELAs and Assistant Registrars in assessing risk in cases involving single clinical incidents and concerns.
- 10** The provisional enquiry guidance at Annex B has been updated to include specific consideration to be taken by Assistant Registrars in dealing with single clinical incidents and concerns.

Risks

- 11** Key to the success of this project is ensuring that decisions to close cases at triage are robust and effective. We will deliver robust training for Assistant Registrars on identifying cases involving single clinical incidents and concerns that should be referred for a full investigation. The process will also be piloted and carefully monitored.

Next steps

- 12** Siebel system requirements are to be submitted by January 2016. Training on the new provisional enquiry process and enhanced triage guidance will begin in April 2016, with operational processes finalised (including audit and management information reporting) in January 2017.

Equality and Diversity

- 13** Based on an analysis of cases undertaken for phase one of the Rule 4(4) project, we know that between May 2013 and April 2014, male doctors, black and minority ethnic doctors and international medical graduates were all overrepresented in stream one cases that closed with no further action.

- 14** We expect that the enhanced triage guidance will mean that a percentage of cases that would previously have been referred for a full investigation will in future not be referred for investigation. This should reduce disadvantage for doctors overrepresented in these cases.

8 – Enhanced Triage Guidance – Single Clinical Incidents

8 – Annex A

Single Clinical Incidents and concerns – thresholds guidance (draft)

Introduction

- 1 The purpose of this guidance is to assist assistant registrars who make rule 4 decisions (“decision makers”) when considering whether we should undertake an investigation in response to a single clinical incident or concern.
- 2 A single clinical incident is defined as one relating to a single instance of treatment with regard to one patient.
- 3 A single clinical concern is defined as concerns relating to more than one point of contact but only a single issue or course of treatment.
- 4 Our experience has shown that only a small minority of single clinical incidents or concerns require us to take action, and in most cases, single clinical incidents or concerns that have been managed appropriately locally do not pose an ongoing risk to patients or public confidence in doctors.
- 5 The guidance is intended to assist decision makers in:
 - a identifying single clinical incidents and concerns;
 - b deciding whether an investigation is necessary.
- 6 This guidance is designed to be used in conjunction with Guidance on categorising Stream 1, Notify RO or Employers and Guidance on allocating cases to NIT or RIT and Provisional Enquiries decision makers’ guidance.

Identifying a single clinical incident or concern

- 7 When assessing a complaint or referral at the triage stage, the decision maker should follow this guidance to identify a single clinical incident or concern.
- 8 A single clinical incident will usually:

- relate to the care of a single patient, and;
 - comprise a concern involving (only) a single consultation, event or procedure.
- 9 Where a doctor has seen a patient on multiple occasions, this should not be considered a single clinical incident, even where the concern relates to a single condition issue or course of treatment.
- 10 A single clinical concern will usually:
- Relate to the care of a single patient, and;
 - comprise a concern involving more than one point of contact but only a single condition, issue or course of treatment.
- 11 In some cases, where the decision maker lacks the appropriate medical knowledge to assess the nature of the interaction between the doctor and patient, it may be necessary to seek a medical opinion from a case examiner. This should be done in line with existing triage guidance.

Rule 4 decision

- 12 Because of the nature of single clinical incidents or concerns, it may be appropriate for the concern to be addressed locally, without requiring us to initiate an investigation.
- 13 In many cases, where an enquiry relates to a single clinical incident or concern we will not need to undertake a full investigation and it will be appropriate to close the enquiry at triage stage, either with or without the need for a Provisional Enquiry. A decision maker should, in the circumstances of the complaint/referral, first consider the information that has been provided and whether it is sufficient to support an informed and objective decision.
- 14 When an enquiry is identified as a single clinical incident or concern, the decision maker should look to either:
- a close the enquiry,
 - b open an investigation and assign it to an investigation stream¹,
 - c assign it to the provisional enquiry team, who will make limited enquiries under Rule 4(4) to ascertain whether or not the concern requires full investigation.

Factors that suggest an investigation may not be necessary

- 15 If sufficient objective information is available at the enquiry stage, either before or following a provisional enquiry to conclude that a single clinical incident or concern

¹ See *Guidance on categorising Stream 1 and Notify RO or Employers*

does not raise a questions about a doctor's fitness to practise, the GMC does not need to conduct its own investigation and local management is appropriate.

- 16** Where the doctor's involvement was material to the concern (taking account of any wider systems errors), the decision maker should consider the following factors, to determine whether the matter raises a question about the doctor's fitness to practise and it is not necessary to conduct an investigation.

Factors that suggest an investigation is unlikely to be required:

- a** The matter is not so serious (taking account of the recognised complication of a procedure) that exceptional action may be required in response to a single incident to uphold public confidence in doctors, for example, because the doctor has shown reckless disregard for patient safety. An RO's view will be important in assessing this.
- b** The matter does not appear to be part of a wider pattern of concern about the doctor or their teams that raises a question about the doctor's fitness to practise. This will include any previous GMC fitness to practise history.
- c** Repetition is unlikely because:
 - i** the doctor has demonstrated insight and responded cooperatively with local reviews or investigations,
 - ii** there is no clear and ongoing risk to patients that local action is insufficient to address. This will include considering what action (including disciplinary action) if any has been, or is being, implemented locally and the extent of involvement of independent experts in investigating the incident.

- 17** Where all these factors are present at the time of a Rule 4 decision, it will indicate that the single clinical incident or concern presents little or no risk to patient safety.

Factors that suggest an investigation may be required

- a** The matter is sufficiently serious (taking account of the recognised complication of a procedure) that exceptional action may be required in response to a single incident to uphold public confidence in doctors, for example, because the doctor has shown reckless disregard for patient safety.
- b** The matter appears to be part of a wider pattern of concern about the doctor or their teams, including the doctor's previous fitness to practise history.
- c** Repetition appears likely because:

- i the doctor has failed to demonstrate insight or respond cooperatively with local investigations,
- ii there is clear and ongoing risk to patients. This will include considering what action (including disciplinary action) if any has been or is being implemented locally and the extent of involvement of independent experts in investigating the incident.

18 The presence of one these risks at the time of a Rule 4 decision will indicate that the single clinical incident or concern may present a risk to patient safety. However, the decision maker will take all relevant factors into account when determining whether an investigation is required.

Referral to Provisional Enquiry Team

- 19** Where there is insufficient information available to make an informed and objective decision on the closure or promotion of a complaint/referral, it should be referred to the Provisional Enquiry (PE) team, where limited investigations can be made in order to ascertain whether or not an investigation is required.²
- 20** The PE team will gather relevant information under Rule 4(4) (eg. clarification from a doctor's RO). The PE Investigation Manager will then decide under Rule 4 whether the case can be closed at enquiry stage, or requires investigation. In coming to this decision, the PE IM will apply the same considerations detailed at paragraphs 12-14 above.
- 21** Before considering a referral to the PE team, decision makers should refer to the *Provisional Enquiries Guidance*.

² Decision Makers should have regard to paragraphs xx – xx of the Provisional Enquiries Guidance before making such a referral.

8 – Annex B

Single Provisional Enquiries (Rule 4(4))

Introduction

- 1 This guidance is supplementary to the *Guidance on categorising Stream 1, Notify RO and Notify Employer and Allocating cases to the National Investigation Team and the Regional Investigation Teams*. It is intended to support assistant registrars (ARs) in deciding whether further enquiries should be made under Rule 4(4), clarifying the situations in which it is appropriate to make further enquiries and the types of information that can be obtained.
- 2 Our overarching objective in exercising our statutory functions, as a regulator, is to protect the health and safety of the public and the public interest. One of the ways we do this is by identifying and addressing a doctor's fitness to practise issues in a proportionate and targeted way.
- 3 Making enquiries under Rule 4(4) can enable us to make better informed decisions about whether an investigation is needed.

Principles

- 4 Rule 4(4) provides an explicit power for the registrar (delegated to assistant registrars) to make further enquiries before making a decision at triage. The AR can:
 - '...carry out any investigations as in his opinion are appropriate to the consideration of:
 - a whether or not the allegation falls within section 35C(2) of the Act;
 - b the practitioner's fitness to practise; or
 - c the matters outlined within paragraph 5 ... [Rule 4(5) the five year rule].'

- 5** Subject to the limitations referred to below at paragraph 12, this guidance provides for the AR to make further enquiries in situations where:
- d** the allegation (in the complaint or referral) itself is unclear
 - e** more information is needed to clarify whether the allegation raises a fitness to practise issue, for example, if the allegation appears misconceived, or in the context of a clinical incident or concern, if the allegation was a widely accepted complication or risk or is part of a wider pattern of concerns
 - f** on the face of it, there is an allegation which raises a fitness to practise issue, but the evidence may be unlikely to support a finding of impairment and further information is needed to clarify whether the allegation is capable of raising a question of impaired fitness to practise,
- 6** In relation to (a) above, the AR must make sufficient reasonable enquiries to enable them to make a decision. Examples of clarification will include identifying relevant doctors, obtaining documents missing from the information received to date and/or clarification of places and dates from a complainant or referrer.
- 7** In relation to (b) above many allegations falling within this category are likely to relate to clinical failings or single clinical incidents or concerns. The AR can make enquiries under Rule 4(4) to clarify whether the concerns raised would require us to conduct an investigation (because they raise a question about the doctor's fitness to practise). This may include obtaining relevant medical records, clarification from the doctor's Responsible Officer (RO), opinions from a medical case examiner (CE) and/or external experts.
- 8** In relation to (c) above, allegations based on which the evidence is unlikely to support a finding of impairment are those where, despite appearing to be serious, it seems likely that evidence, which can be easily obtained within Rule 4(4), would reveal that the allegation is unsupported and therefore not capable of raising a question of impaired fitness to practise. These allegations are often likely to involve misconduct.
- 9** In categories 5 (b) and (c) above, a case is suitable for Rule 4(4) if it appears likely that clarification can be achieved by obtaining one or two discrete pieces of information on the basis that the information can be obtained within a reasonable period of time. It may be appropriate to discuss these timescales with the relevant ELA where the information is held by a Trust/Board.

Suitability

- 10** Every enquiry should be considered on a case by case basis. However, the AR may find it useful to bear the following principles in mind when deciding whether or not a provisional enquiry (PE) is appropriate.

11 A PE may be considered suitable where:

- a** an allegation appears confused or may be based on a misperception and we can contact external sources for clarification
- b** an allegation is clear but it contains information that suggests that it may not raise questions about a doctor's fitness to practise
- c** local or third-party investigation information is available which could help us determine whether there is a fitness to practise issue. For example, a local investigation of a single clinical incident or concern.

12 A PE is unlikely to be appropriate where:

- a** we have clear information from the complainant that raises a question about the doctor's fitness to practise that meets the threshold for a full investigation
- b** the concerns are such that we would ordinarily close the case (ie rule 4(4) should not be used to validate a decision to close the case where the criteria for closure are met)
- c** an enquiry is linked to an existing investigation, where it may be more suitable to link the allegation to the existing case
- d** the incident giving rise to the allegation predates another concluded case about the same doctor and the concerns have been dealt with
- e** there is a significant dispute about the facts or an allegation of dishonesty that can only be resolved by establishing credibility through witness testimony or otherwise cannot be resolved by obtaining a discrete piece of information
- f** the concerns relate to systemic issues rather than fitness to practise issues.

The purpose of making provisional enquiries at Rule 4(4)

- 13** The purpose of making provisional enquiries at Rule 4 (4) is not to establish whether the realistic prospect test is met (i.e. there is a 'realistic prospect' of the allegation being proved') but to determine whether the allegation raises a fitness to practise issue.
- 14** Where the allegation is clear and/or there is sufficient information to make a decision, the AR should make a decision to close or promote the allegation following the usual procedure under Rule 4.

Information suitable for provisional enquiry

Medical records

- 15 It is acknowledged that, in the majority of clinical cases, relevant medical records will exist. Given the timeframe within which provisional enquiries will be conducted, it is likely that we will ask for only relevant extracts from medical records and only from relevant sites.
- 16 In cases where medical records have been identified as the discrete information necessary to make a decision under Rule 4(4), the AR, with advice from a medical CE where appropriate, the AR should clarify the extent and type of medical records required in order to assist operational staff.

Clarification sought from a doctor's Responsible Officer

- 17 In some cases (eg. single clinical incidents or concerns¹), we can make simple enquiries of the doctor's RO, seeking confirmation about the nature of the incident and what has happened since the incident, before deciding whether an investigation is required.
- 18 For a single clinical incident or concern, an IO will make standard enquiries of ROs using a standard letter template, attached at Annex A.
- 19 Where a doctor's RO is not aware of an incident or concern or has not had sufficient time to complete necessary local enquiries into the incident, we should still send them the template letter and where they are not able to answer some or all of the questions we should consider within the provisional enquiries process how we might obtain that information including obtaining medical records and an expert opinion. Where specific information can only be obtained from an RO, the ELA should approach the RO directly to seek to obtain that information (for example, where a local investigation has not been carried out or no expert input has been provided at that investigation, we are likely to seek our own expert input but will still want the RO to confirm if there are other concerns about the doctor or to provide specific information that our expert may require).
- 20 Where a local investigation is *already underway*, it may be appropriate to wait for the investigation to be completed, however this will only be appropriate where the conclusion of the investigation is imminent (expected within two weeks of the referral for a provisional enquiry). ROs should be asked to disclose information to us on an ongoing basis to avoid delay and cases should be reviewed weekly to ensure that they are not delayed awaiting an RO investigation. Where a delay of longer than two weeks is likely, the process set out in the above paragraph should be followed.

Oral or written enquiries with individuals/organisations

- 21** These may be relatively quick enquiries that the AR (or delegated staff resource) can undertake in order to understand the nature of a complaint or referral. The Threshold guidance states:

“local enquiries may be more appropriate to establish whether the allegations arise out of a misunderstanding or whether there has been apparent misconduct by the doctor that we need to consider”²

Formal investigations by public bodies (e.g. other regulators, coroners, National Fraud Office)

- 22** We may receive a complaint/referral that concerns the outcome of a formal process. We should obtain a copy of any report if the complaint/referral gives us reason to believe that it will help us to understand the issue(s); and the report has been produced by a credible body.
- 23** Given the timeframe of the provisional enquiry process, consideration should be given to whether or not the investigation is complete and, therefore, the report available. If it is not clear from the complaint whether or not a report is available, the AR should contact the investigating body to ensure that it can be requested within the timeframe.

Medical CE advice and Expert Opinion

- 24** After obtaining medical records, or relevant third party information, an IO will need to seek either medical CE advice, or the opinion of an external expert. The AR should indicate which is likely to be appropriate to the enquiry.

Medical Case Examiner advice

- 25** To help determine whether there is a (clinical) issue that warrants investigation, a medical CE can be asked to advise whether the doctor's actions raise a question about their fitness to practise. It will be appropriate to request advice from a medical CE regarding general issues or, in the case of a specialist concern, where they have the appropriate specialism.
- 26** At this stage, the medical CE is not being asked to advise whether the RPT is met. The medical CE may be asked to advise whether the concerns raise a question about the doctor's fitness to practise that requires further investigation.

²Paragraph 13 to the Thresholds.

Medical expert opinion

- 27** To help determine whether there is a (clinical) FTP issue, the AR can ask for a medical expert opinion. It will be appropriate to refer to a medical expert for an opinion where we do not have the specialist expertise within the GMC.
- 28** At this stage, the medical expert is not being asked to assess the standard of care but rather whether, on the face of it, the concerns raise a question about the doctor's fitness to practise that requires further investigation.
- 29** In single clinical incident or concern cases, where a doctor does not have a RO, it will be appropriate to seek an independent expert opinion supported by medical records. In this instance, the IO will request that the expert provide an opinion on the factors listed at paragraph 18.

Lay Case Examiner

- 30** To help delineate/articulate the issues within a complaint/referral, a lay CE can be asked for advice. At this stage, the CE is not being asked to advise whether the RPT is met but whether the concerns raise a question about the doctor's fitness to practise that requires further investigation.

Considerations for AR

- 31** The AR may be able to give some indication, based on the nature of the allegations, which of the above ought to be sought during a provisional enquiry. The AR should consider the complexity of the allegations and the specialist input required.
- 32** The AR may on occasion feel it is appropriate to initially seek the opinion of a medical CE on whether or not an expert opinion is required. This will be useful where the AR has insufficient specialist knowledge to determine whether an external expert opinion will be useful, or what specialist input is required.

Consent and disclosure

Consent

- 33** If we propose to share sensitive information that relates to the complainant or a third party with external individuals or organisations as part of provisional enquiries we will need to seek consent from the complainant.
- 34** The online complaints form, and the PDF and Word versions of the form, ask for consent to make provisional enquiries. Where a complaint is made using the online form, assuming the complainant is the patient, the issue of consent will have been dealt with.

- 35** Where a complaint is made without using the online form, or the PDF or Word versions of the form, in light of the pressing need to ensure provisional enquiries are conducted quickly to enable the matter to be triaged, we will write to the complainant to seek consent to disclose the information contained in the complaint and ask for a response by a date specified.
- 36** If the complainant has not responded by the date provided in the letter, information can be shared if there is justification to do so. As we have not, at this stage, been able to assess the nature and/or seriousness of the concern, disclosure without consent will usually be justified in these circumstances. The AR should provide reasons for proceeding without consent and the complainant should be notified.
- 37** If the complainant refuses consent (including in the online form, PDF or Word version) our normal process for cases where consent is refused applies. We will need to consider any reasons provided by the complainant for refusing consent and decide whether there is justification to override the refusal to provide consent in the circumstances. As we have not, at this stage, been able to assess the nature and/or seriousness of the concern, unless there are concerns about harm to the complainant or a third party that would override our public interest role, disclosure without consent will usually be justified. The AR should provide reasons for proceeding without consent and the complainant should be notified.
- 38** If the complaint has been referred by a Trust and contains sensitive information, our usual consent policy applies. We should contact the Trust in relation to consent. If the referral contains sensitive information about multiple (3 or more) patients we can conduct provisional enquiries while simultaneously contacting the Trust to ask if consent has been provided to share the information.

Disclosure

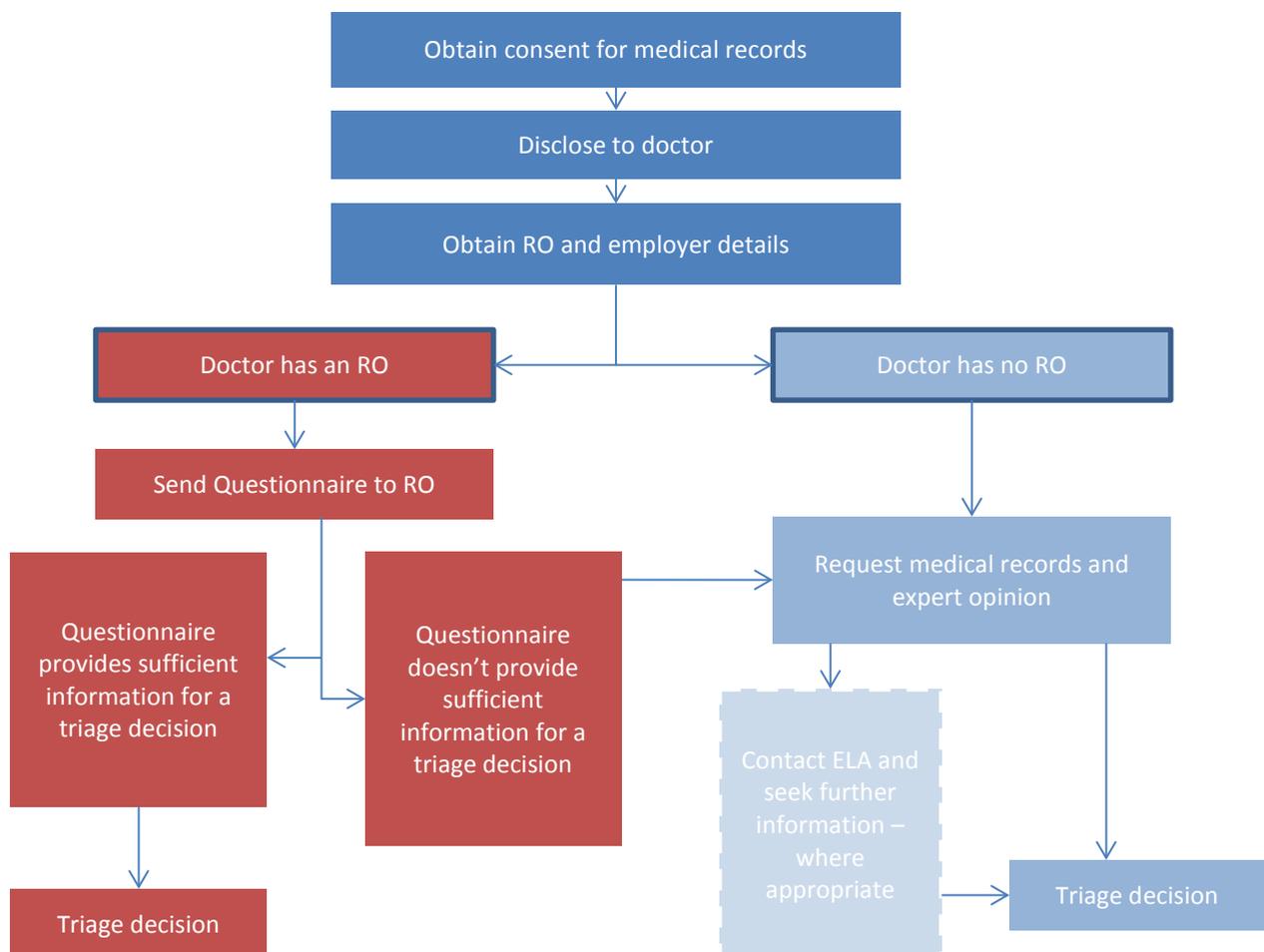
- 39** The doctor should be notified before we conduct any external enquiries.
- 40** There is no requirement under the *Fitness to Practise Rules* for the GMC to notify a doctor's employer of a PE made under Rule 4(4) (a) or (b)³. The decision maker will need to consider whether or not a disclosure is required in order to request information from a doctor's employer. Disclosure to the doctor's employer(s) will be required in the event that an investigation is opened following a PE.
- 41** A doctor's Responsible Officer should be notified of a PE regardless of whether or not information is required.

³ S35A(2) of the *Medical Act* and Rule 13 of the *Fitness to Practise Rules*

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8 – Annex C

Diagram of process



RO: Responsible Officer

ELA: Employer Liaison Adviser